



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 10/774,681   | 02/08/2004  | Michael Scott Ehrlich | E0444.70000/US01    | 9429             |
| 23628 7590 04/20/2009<br>WOLF GREENFIELD & SACKS, P.C.<br>600 ATLANTIC AVENUE<br>BOSTON, MA 02210-2206 |             |                       |                     |                  |
| EXAMINER   |             |                       |                     |                  |
| CLOW, LORI A   |             |                       |                     |                  |
| ART UNIT   |             | PAPER NUMBER          |                     |                  |
| 1631   |             |                       |                     |                  |
| MAIL DATE  |             | DELIVERY MODE         |                     |                  |
| 04/20/2009   |             | PAPER                 |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/774,681

**Applicant(s)**

EHRlich, MICHAEL SCOTT

**Examiner**

LORI A. CLOW

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 25 and 28-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 and 28-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' response, filed 6 February 2009, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### **Claim Status**

Claims 1-5, 25, 28-38 are currently pending. Claims 1-5, 37 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5 March 2007.

Claims 6-24, 26, and 27 have been cancelled. Claims 25 and 28-36 are examined herein.

#### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25 and 28-35 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,384,239 (Saunders; Publication date of January 24, 1999), as set forth in the previous Office Action and re-iterated below.

The instant claims, as amended, are drawn to a method of obtaining information about the blood glucose level history of a patient at predetermined time intervals. The method comprises steps of: obtaining a sample of red blood cells (RBCs); sorting the RBCs to measure glycated hemoglobin to generate a cell distribution profile that is divided into a series of consecutive bins each containing a number of cells representing a predetermined time interval; calculating a difference between glycated hemoglobin levels at each edge of the bin; and converting the calculated difference in glycated hemoglobin levels into blood glucose levels.

In regard to claim 25, Saunders teaches obtaining RBCs from a patient (column 4, lines 6-7); sorting the RBCs to measure glycated hemoglobin (column 4, line 13-32); generating a cell distribution profile (column 3, line 19 which teaches **time resolved** glycated hemoglobin; column 4, lines 6-12, which teaches RBC age and glycation **rate over time**; column 4, lines 19-33); and dividing cell distribution into bins (column 8, line 64, which teaches fractionations; column 9, line 9, line 1, which teaches that samples of cells are sets. This is fairly interpreted to encompass the same limitation as "bin", as "bins" are not specifically defined in the specification). Further, in relation to the newly added limitations, Saunders teaches that blood glucose levels are related to the slope of the time-resolved glycohemoglobin curves (column 13, example), thereby teaching correlation of glycated hemoglobin with glucose levels.

In regard to claim 28, Saunders teaches an algorithm that corrects for non-linearity in glycation rate (column 7, lines 29-37).

In regard to claim 29, Saunders teaches an algorithm for patient specific data (fairly interpreted as any data from the patient, including PK levels) (column 7, lines 39-67).

In regard to claim 30, Saunders teaches age and gender specifics at column 10, lines 16-23).

In regard to claim 31, Saunders teaches an algorithm for the values of an average life span of a RBC at column 10, line 53 GHb related to age of RBCs).

In regard to claim 32, Saunders teaches sorting using chromatography (column 4, lines 55-56).

In regard to claim 33, Saunders teaches using the information about blood glucose history to assist in determination of patient diabetes at column 12, line 35).

In regard to claims 34, Saunders teaches determining an anti-diabetic treatment regimen based on blood glucose level history (column 15, lines 5-30).

In regard to claim 35, Saunders teaches obtaining more than one sample (as in a second sample) (column 10, lines 5-41).

### ***Response to Applicant's Arguments***

1. Applicant argues that "Saunders fails to teaches generating time-resolved glycohemoglobin curves by methods that are not based on the amount of glycated hemoglobin". Applicant further characterizes the Saunders patent as "failing to teach or suggest using detected amounts of glycated hemoglobin in intact red blood cells to sort cells by age".

This is not persuasive. As is stated above, Saunders teaches that blood glucose levels are related to the slope of the time-resolved glycohemoglobin curves (column 13, example) and therefore teaches both time interval and glucose level related to glycated hemoglobin. Further, the age evaluation of a cell as it relates to glycated hemoglobin is a measure of glycated

hemoglobin over a time interval. Finally, the claims do not require that glycated hemoglobin in intact red blood cells is used to sort cells by age. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

2. Applicant argues that, with respect to generating a cell distribution profile and dividing cell distribution into bins that "none of these passages recited in Saunders) teach or suggest using glycated hemoglobin levels to generate a cell distribution profile that is divided into bins.

This is not persuasive. As bins are defined only as "each bin containing a plurality of cells corresponding to a time period", Saunders teaches that cell samples are collected and sets are established that represent time intervals (col. 8, lines 65-67; see also Figures 3 and 4 which show cells over time interval and percent of GHB.

The rejection is hereby maintained.

#### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 and 36 remain rejected under 35 U.S.C. 103(a) as being unpatentable over 5,384,239 (Saunders; Publication date of January 24, 1999), as applied to claim 25 above, in view of US PGPUB 20040214243 (Burshteyn et al; filing date of 25 April 2003), for the reasons set forth in the previous Office Action and re-iterated below.

In regard to claim 25, Saunders teaches obtaining RBCs from a patient (column 4, lines 6-7); sorting the RBCs to measure glycated hemoglobin (column 4, line 13-32); generating a cell distribution profile (column 3, line 19 which teaches time resolved glycated hemoglobin; column 4, lines 6-12, which teaches RBC age and glycation rate over time; column 4, lines 19-33); and dividing cell distribution into bins (column 8, line 64, which teaches fractionations; column 9, line 9, line 1, which teaches that samples of cells are sets. This is fairly interpreted to encompass the same limitation as "bin", as "bins" are not specifically defined in the specification). Further, in relation to the newly added limitations, Saunders teaches that blood glucose levels are related to the slope of the time-resolved glycohemoglobin curves (column 13, example), thereby teaching correlation of glycated hemoglobin with glucose levels.

Saunders does not specifically teach "labeling" the glycosylated hemoglobin, as in claim 36. However, Burshteyn et al. do teach a method of analyzing hemoglobin in a sample using a pan-hemoglobin antibody conjugated to a detectable marker (abstract; paragraph 0014; paragraph 32; paragraph 41).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used a label, such as that of Burshteyn, in the method of Saunders for separation of glycosylated cells. One would have been motivated to do so because such methods were well known in the art at the time of the invention and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions. Further, Saunders readily contemplates and teaches that separations are done by a variety of methods (column 4, lines 55-67). One of skill in the art could have easily substituted the separation by antibody affinity in the affinity chromatography method of Saunders because all of the claimed elements were known, in the prior art, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.

### ***Response to Applicant's Arguments***

1. Applicant argues that "Burshteyn et al. also fails to suggest or teach methods that use a detected amount of glycosylated hemoglobin in intact red blood cells to determine both a time interval and a glucose level".

This is not persuasive, for the reasons set forth above pertaining to Saunders, who does teach the limitations recited. Therefore, the rejection is maintained.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

Art Unit: 1631

problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

April 17, 2009

/Lori A. Clow, Ph.D./

Primary Patent Examiner

Art Unit 1631